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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,658	01/16/2004	Marc Elliot Rothenberg	CMC -162	8032

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WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,658	ROTHENBERG, MARC ELLIOT	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-32* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 16-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13 and 15-32* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/04;7/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 08 September 2006 has been entered in full. Claim 11 is amended. Claim 14 is cancelled.

Election/Restrictions

Applicant's election with traverse of the species of type of RELM detection (RELMβ protein) and species of patient parameter (clinical status) in the reply filed on 08 September 2006 is acknowledged. The traversal is on the ground(s) that the search of the method with RELMα and RELMβ will necessarily disclose art encompassing the species. This is found to be persuasive in part in view of Applicant's argument and upon further consideration by the Examiner. Specifically, the species requirement for RELM inhibition/detection is hereby *withdrawn*. The species of RELM inhibition/detection are rejoined (claim 13).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 16-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08 September 2006.

Claims 11-13 and 15 are under consideration in the instant application as they read upon the elected species of clinical status.

Specification

1. The disclosure is objected to because of the following informalities:

2. The Brief Description of the Drawings does not refer to Figures 2A-2C, 3A-3H, 4A-4E, 5A-5C, 6A-6D, 7A-7E, 8A-8C, and 9A-9G.

Appropriate correction is required.

Claim Objections

3. Claims 11-13 and 15 are objected to because of the following informalities:

3a. Claims 11-13 and 15 recite non-elected species.

3b. In claim 11, the end of line 3, the term "pulomonary" is misspelled.

Appropriate correction is required.

35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The terms "pulmonary inflammatory process" and "chronic repair process" in claims 11-13 and 15 are relative terms which render the claims indefinite. The terms "pulmonary inflammatory process" and "chronic repair process" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It cannot be determined what is encompassed by the terms "pulmonary inflammatory process" and "chronic repair process". For example, do the terms encompass diseases, disorders, conditions, pathways?

7. Claims 11-13 and 15 are indefinite because the step in claim 11, lines 6-7 does not match or clearly relate back to the preamble. For instance, the preamble in claim 11 recites "a physiological assessment method" while the last step recites "an increased level of at least one of RELMα or RELMβ indicates a pulmonary inflammatory process or chronic repair process". (Please note that this issue could be overcome by amending the preamble of claim 11 to recite, for example, "A physiological assessment method for determining the presence of a pulmonary inflammatory process or chronic repair process in a patient comprising...".)

8. The term "clinical status" in claims 11-13 and 15 is a relative term which renders the claims indefinite. The term "clinical status" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what is encompassed by this term. For example, disease diagnosis? Disease progression?

9. Claim 12 is rejected as being indefinite because it is not clear how the biological samples recited in the claim relate back to or further limit claim 11, from which claim 12 depends. For example, are the biological samples recited in claim 12 considered to be types of pulmonary tissue (as recited in claim 11, line 3)?

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 11-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of determining allergic pulmonary inflammation in a subject comprising (a) measuring RELMα mRNA or protein expression or RELMβ mRNA expression in a biological sample isolated from a subject, wherein the biological sample is lung fluid, lung biopsy, or bronchoalveolar fluid and (b) comparing RELMα mRNA or protein expression or RELMβ mRNA to normal lung, wherein an increased level of RELMα mRNA or protein expression or RELMβ mRNA as compared to normal lung indicates the presence of allergic pulmonary inflammation, *does not reasonably provide enablement for* a physiological assessment method comprising determining a level of at least resistin-like molecule α (RELMα) or resistin-like molecule β (RELMβ) in a pulmonary tissue of a patient to assess a patient parameter indicative of a pulmonary disease, wherein the parameter is clinical status, and wherein an increased level of at least RELMα or RELMβ indicates a pulmonary inflammatory process or chronic repair process in the patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a physiological assessment method comprising determining a level of at least resistin-like molecule β (RELMβ) in a pulmonary tissue of a patient to assess a patient parameter indicative of a pulmonary disease, wherein the parameter is clinical status, and wherein an increased level of at least RELMβ indicates a pulmonary inflammatory process or chronic repair process in the patient. The claims also recite that RELMα or RELMβ is determined in at least one of lung fluid, lung biopsy, sputum, mucus, nasal washings, bronchoalveolar fluid, respiratory tract tissue, respiratory tract fluid, blood, and combinations

thereof. The claims recite that RELMα or RELMβ is determined qualitatively, quantitatively, or functionally.

The specification of the instant application teaches that the level of mRNA for RELMα and RELMβ is evaluated in lung from mice challenged with different allergens in different models of allergen-induced asthma (pg 7, lines 10-24 through pg 10; pg 17). The specification discloses that expression of RELMα and RELMβ mRNA is significantly increased during allergen induced asthma compared to control mice (pg 16, lines 22-24; pg 17, lines 10-24 through pg 18; Figures 1-2). The specification also teaches that allergic lung inflammation is associated with marked and specific ectopic expression of RELMβ in the lung, which is in contrast to prior work (pg 26, lines 8-12). The state of the art also teaches that expression of mFIZZ1 (RELMα) mRNA and protein in murine lungs with OVA-induced allergic inflammation is increased as compared to control (see Holcomb et al. EMBO J 19(15): 4046-4055, 2000; pg 4048, col 1, 2nd paragraph; pg 4049; Figures 4-6). However, the specification of the instant specification does not teach any methods or working examples that indicate an increased level of RELMα or RELMβ in all possible pulmonary tissues of a patient is associated with a patient's clinical status of all possible pulmonary diseases or indicates a pulmonary inflammatory process or chronic repair process in the patient. Undue experimentation would be required to determine such. There is little or no guidance in the specification indicating what specific pulmonary tissues are utilized in the assay (other than lung fluid, lung biopsy, or bronchoalveolar fluid) and which specific pulmonary diseases and pulmonary inflammatory process/chronic repair process are to be assessed or evaluated in the patient. Relevant literature teaches that there are several diseases related to the lungs, including asthma, emphysema, chronic obstructive pulmonary

disease, cystic fibrosis, and pulmonary arterial hypertension, among others (see for example, Appendix A attached to the instant Office Action). Undue experimentation would be required of the skilled artisan to determine if increased RELMα or RELMβ levels are indicative of all possible pulmonary diseases.

Additionally, the present invention is unpredictable and complex wherein one skilled in the art may not necessarily assess a patient's clinical status indicative of a pulmonary disease or indicate a pulmonary inflammatory process/chronic repair process by determining the level of RELMβ protein. As discussed above, the specification of the instant application measures the level of *mRNA* for RELMα and RELMβ in lung from mice challenged with different allergens (pg 7, lines 10-24 through pg 10; pg 17). However, the specification provides little or no guidance as to how to measure RELMα or RELMβ qualitatively or functionally, as required by claim 15. Furthermore, undue experimentation would required of one skilled in the art to determine RELMβ *protein* expression levels in the tissue of a patient, as required by claim 13. The state of the art is such that protein expression levels are not predictable from the mRNA expression levels. For example, Lilley et al. teach that "DNA chips (mRNA profiling studies) can contribute to the study of gene expression in response to a particular biological perturbation. However, the extrapolation that changes in transcript level will also result in corresponding changes in protein amount or activity cannot always be made" ("Proteomics" Molecular Biology in Cellular Pathology, (2003) England: John Wiley & Sons, page 351). King et al. disclose that "it has been established that mRNA levels do not necessarily correlate with protein levels" (pg 2287, 2nd full paragraph). King et al. state that it has been demonstrated that correlation between mRNA and protein abundance is less than 0.5 and that "mRNA expression studies should be

accompanied by analyses at the protein level" (pg 2287, bottom of col 1 through the top of col 2). Haynes et al. teach that "[p]rotein expression levels are not predictable from the mRNA expression levels" (pg 1863, top of left column) and "only the direct analysis of mature protein products can reveal their correct identities, their relevant state of modification and/or association and their amounts" (pg 1870, under concluding remarks).

Due to the large quantity of experimentation necessary to determine an association between an increased level of RELMα or RELMβ in all pulmonary tissues of a patient and a patient's clinical status of all possible pulmonary diseases or to indicate a pulmonary inflammatory process or chronic repair process in the patient; the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations as to the type of pulmonary tissue, pulmonary disease, and pulmonary inflammatory process/chronic repair process, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

11. Claims 11-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a physiological assessment method comprising determining a level of at least resistin-like molecule β (RELMβ) in a pulmonary tissue of a patient to assess a

patient parameter indicative of a pulmonary disease, wherein the parameter is clinical status, and wherein an increased level of at least RELMβ indicates a pulmonary inflammatory process or chronic repair process in the patient. The claims also recite that RELMα or RELMβ is determined in at least one of lung fluid, lung biopsy, sputum, mucus, nasal washings, bronchoalveolar fluid, respiratory tract tissue, respiratory tract fluid, blood, and combinations thereof. The claims recite that RELMα or RELMβ is determined qualitatively, quantitatively, or functionally.

The specification of the instant application teaches that the level of mRNA for RELMα and RELMβ is evaluated in lung from mice challenged with different allergens in different models of allergen-induced asthma (pg 7, lines 10-24 through pg 10; pg 17). The specification discloses that expression of RELMα and RELMβ mRNA is significantly increased during allergen induced asthma compared to control mice (pg 16, lines 22-24; pg 17, lines 10-24 through pg 18; Figures 1-2). However, the brief description in the specification of one example of a pulmonary disease (asthma) is not adequate written description of an entire genus of methods of determining the level of RELMβ to assess a patient's clinical status for a genus of pulmonary diseases and a genus of pulmonary inflammatory processes or chronic repair processes. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. However, in the absence of sufficient recitation of distinguishing identifying characteristics, the instant specification does not provide

adequate written description for the claimed genus of methods of assessing/indicating pulmonary diseases and pulmonary inflammatory processes or chronic repair processes.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the pulmonary diseases and pulmonary inflammatory processes or chronic repair processes of the encompassed method, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The pulmonary disease and pulmonary inflammatory process or chronic repair process is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a method of determining the level of RELMα or RELMβ to indicate a specific pulmonary disease and/or specific pulmonary inflammatory process or chronic repair process, but not the full breadth of the claims meets the written description provision of 35

U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

12. Claims 11-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to a physiological assessment method comprising determining a level of at least resistin-like molecule β (RELMβ) in a pulmonary tissue of a patient to assess a patient parameter indicative of a pulmonary disease, wherein the parameter is clinical status, and wherein an increased level of at least RELMβ indicates a pulmonary inflammatory process or chronic repair process in the patient. The claims also recite that RELMα or RELMβ is determined in at least one of lung fluid, lung biopsy, sputum, mucus, nasal washings, bronchoalveolar fluid, respiratory tract tissue, respiratory tract fluid, blood, and combinations thereof. The claims recite that RELMα or RELMβ is determined qualitatively, quantitatively, or functionally.

The specification as originally filed does not provide adequate written description for "a pulmonary disease" and "a pulmonary inflammatory process". These phrases are not expressly asserted, nor does they flow naturally from the specification. It is noted that the Examiner could not find support for these phrases at pg 4, line 15 through pg 5, line 2, as indicated by Applicant in the 08 September 2006 Response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 11-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Holcomb et al. (EMBO J 19(15): 4046-4055, 2000).

Holcomb et al. teach determining the level of FIZZ1 (RELMα) mRNA and protein in bronchoalveolar lavage fluid (BALF) from mice with experimentally-induced allergic pulmonary inflammation (pg 4053, bottom of col 1 through col 2). Holcomb et al. disclose that expression of mFIZZ1 mRNA and protein in murine lungs with OVA-induced allergic inflammation is increased as compared to control (pg 4048, col 1, 2nd paragraph; pg 4049; Figures 4-6). Specifically, during allergic pulmonary inflammation, mFIZZ1 expression increases in hypertrophic, hyperplastic bronchial epithelium and in type II alveolar pneumocytes (abstract; pg 4048, col 1-2; pg 4049).

Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Artis et al. Proc Natl Acad Sci USA 101(37) : 13596-13600, 2004 (RELMβ is up-regulated in the GI tract after exposure to nematode infections and inhibits nematode chemotaxis *in vitro*)

Beltowski et al. MedSci Monitor 9(2) : RA55-61, 2003 (review of resistin and resistin-like/FIZZ molecules)

Steppan et al. Proc Natl Acad Sci USA 98(2): 502-506, 2001 (RELMα and RELMβ mRNA expression study)

Hogan et al. J Allergy Clin Immunol 118 : 257-268, 2006 (show that RELMβ is expressed in the colon by goblet cells and enterocytes and has a role in homeostasis; RELMβ plays a role in the regulation of susceptibility to colonic inflammation)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
06 November 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER

- NHLBI Home
- Information for Patients & the Public
  - Diseases and Conditions Index
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  - Lung Information
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- News & Events Center
- About NHLBI

Lung Diseases Information

Topics from the Diseases and Conditions A-Z Index (DCI) are also listed below and identified by this image: DCI TOPIC

Asthma

Publications / Fact Sheets:

- **General**
  - Asthma DCI TOPIC
- **Schools/ Child Care Centers**
  - Suggested Emergency Protocol for Students with Asthma Symptoms
  - Students with Chronic Illnesses: Guidance for Families, Schools and Students
  - NAEPP Resolution on Asthma Management at School
  - Asthma and Physical Activity in the School
  - How Asthma-Friendly Is Your School?
    (¿Su escuela tiene en cuenta a los niños con asma?)
  - How Asthma-Friendly Is Your Child Care Setting?
    (¿Su guardería infantil tiene en cuenta a los niños con asma?)
  - School Health Index--A Self-Assessment and Planning Guide (Centers for Disease Control and Prevention)
  - Additional Resources from NAEPP Member Organizations

See Also:

- National Asthma Education and Prevention Program

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COPD/Emphysema

Web Sites and Interactive Web Applications:

- COPD: Learn More Breathe Better

Publications / Fact Sheets:

- Chronic Obstructive Pulmonary Disease DCI TOPIC
- Chronic Obstructive Pulmonary Disease (COPD) Data Fact Sheet
- National Emphysema Treatment Trial (NETT)

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Other Lung Diseases

Publications / Fact Sheets:

■ **Health topics on this page:**

- Asthma
- COPD/Emphysema
- Other Lung

■ **See also:**

- **Lung Information for Health Care Professionals**
- List of Publications
- Information Center
- National Cancer Institute (for lung cancers)

- Acute Respiratory Distress Syndrome (ARDS) DCI TOPIC
- Bronchiectasis DCI TOPIC
- Bronchopulmonary Dysplasia DCI TOPIC
- Cystic Fibrosis DCI TOPIC
- LAM (Lymphangioleiomyomatosis) DCI TOPIC
- Pulmonary Arterial Hypertension DCI TOPIC
- Sarcoidosis DCI TOPIC

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